IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Newport News Division

DARLA GRESE, Administrator of the
Estate of Kelli Marie Grese, Deceased,
Plaintiff,

v. No. 4:12cv-49-MSD-DEM

UNITED STATES OF AMERICA,
Defendant.

MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE THE EXPERT REPORT AND EXPERT TESTIMONY OF DR. PAUL S. APPELBAUM

I. Introduction

This is a medical malpractice case. On about November 11, 2010, Kelli Marie Grese, plaintiff's decedent, a veteran, committed suicide by taking an overdose of quetiapine (brand name Seroquel). Although decedent was treated by numerous health care providers over the preceding 15 years, the last psychiatrist known to have provided her treatment was William McDaniel, M.D., an employee of the Hampton Veteran's Administration Medical Center (HVAMC) and thus an employee of Defendant United States. Plaintiff alleges that Dr. McDaniel's acts or omissions in treating her caused her death. Defendant denies any negligence.

In support of her claim, plaintiff has submitted the written expert report of Paul S. Appelbaum, M.D. Letter from Paul S. Appelbaum, M.D., to Robert Haddad, Esq. (July 24, 2012), Exhibit 1.[1]

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[1] We include in Exhibit 1 Dr. Appelbaum's seven page letter to Mr. Haddad and the letters to the editor and the article which he attached to that letter, his list of prior testimony and his statement on his compensation. We do not include his sixty-three (63) page *curriculum vitae*, but note that among many other accomplishments Dr. Appelbaum is the Elizabeth K. Dollard Professor of Psychiatry, Medicine, and Law at Columbia University College of Physicians and Surgeons and the former President of the American Psychiatric Association. He is licensed to practice medicine in Massachusetts and Pennsylvania and is board certified in

An expert's written report must contain: "(i) a complete statement of all opinions the witness will express and the basis and reasons for them; [and] (ii) the facts or data considered by the witness in forming them; * * *." Fed.R.Civ.P. 26(a)(2)(B). Since Dr. Appelbaum's report does not conform with Rule 26(a)(2)(B), Dr. Appelbaum's report should be excluded and he should be excluded from testifying at trial pursuant to Fed.R.Civ.P. 37(c)(1), and *Daubert v. Merrell Dow Pharmaceuticals, Inc*., 509 U.S. 579, 589 (1993).

II. Law

A. Medical Malpractice.

As Plaintiff's action is brought pursuant to the Federal Tort Claims Act, the substantive law of the state in which the alleged negligent act occurred, 28 U.S.C. §§ 1346(b) and 2674. Because plaintiff's claim arose at the HVAMC, Virginia substantive tort law applies. *See Id.*

In any negligence case, plaintiff must prove by a preponderance of the evidence: (i) the existence of a duty; (ii) breach of that duty; (iii) proximate cause; and (iv) injury. *Murray v. United States*, 215 F.3d 460, 463 (4th Cir. 2000); *Fitzgerald v. Manning*, 679 F.2d 341, 346 (4th Cir. 1982). In a medical malpractice case, proof of the first three of these elements – what the standard of care is (duty), whether that standard of care has been breached, and the causal link (proximate cause) between the claimed breach and plaintiff's injuries – must ordinarily be established by qualified and admissible expert opinion testimony. *Fitzgerald*, 679 F.2d at 347.

> Put simply, plaintiff must establish: (1) the applicable standard of care, (2) a breach of that standard of care, (3) that this breach proximately caused plaintiff's injuries. To do so, it is well established that expert testimony is ordinarily necessary.

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psychiatry.

Parker v. United States, 475 F.Supp.2d 594, 598 (E.D.Va. 2007) (internal marks omitted).

Admissible medical opinion testimony "must be stated in terms of a 'reasonable degree of medical certainty.'" *Fitzgerald*, 679 F.2d at 350 (internal marks omitted); *Sharpe v. United States*, 230 F.R.D. 452, 460 (E.D.Va. 2005) *See also Bitar v. Rahman*, 630 S.E.2d 319, 323 (Va. 2006) ("medical opinion based on a possibility is irrelevant, purely speculative and, hence inadmissible.") (internal marks omitted).

> . . . [T]he standard of care by which the acts or omissions are to be judged shall be that degree of skill and diligence practiced by a reasonably prudent practitioner in the field of practice or specialty in this Commonwealth, and the testimony of an expert witness, otherwise qualified, as to such standard of care, shall be admitted . . ."

Code of Virginia, 1950, § 8.01-581.20.

> In order to establish a standard of medical care as well as a violation of such standard, expert testimony is required. In order to qualify as an expert, the witness must show familiarity with the "degree and skill" employed by the ordinary, prudent practitioner in the relevant field and community[2]. . . . And this requirement has been strictly applied in Virginia. . . .

Fitzgerald, 679 F.2d at 347. "The appropriate standard of care is established through testimony by expert witnesses familiar with the practice of a reasonably prudent physician practicing in Virginia at the time of the injury." *Sharpe*, 230 F.R.D. at 460.

B. <u>Expert Reports and Opinions</u>.

For a retained expert, Rule 26(a)(2)(B) requires the expert to write a report. This initial expert report is required to "contain a complete statement of all opinions to be expressed and the basis and reasons therefor," along with "the data or other information considered by the witness

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[2] For actions that arose after July 1, 1976, the applicable standard of care is generally based upon the practice "in this Commonwealth," not the community. *Fitzgerald*, 679 F.2d at 346 and n.2.

in forming the opinions." Rule 26(a)(2)(B). "The Advisory Committee's Note to the 1993 amendments to Rule 26 reveal that the report to be provided under Rule 26(a)(2)(B) is to be 'a detailed and complete written report, stating the testimony the witness is expected to present during direct examination, together with the reasons therefore.'" *Sharpe*, 230 F.R.D. at 458 (quoting advisory committee's note).

Discovery responses often failed to adequately inform the other party of the extent of the expert opinions expected to be offered at trial.

> The reason for [the 1993 amendments to Rule 26(a)(2)(B)] was that information disclosed under the former rule in answering questions about the substance of expert testimony was frequently so sketchy and vague that it rarely dispensed with the need to depose the expert and often was even of little help in preparing for a deposition of a witness.

Sharpe, 230 F.R.D. at 458 (quoting advisory committee's note) (internal marks omitted). "Thus, the expert report should be written in a manner that reflects the testimony the expert witness is expected to give at trial." *Id.*

> An expert is expected to 'work diligently to amass the factual data necessary for his expert analysis' and
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> having done that, will prepare and submit a timely and comprehensive report complying fully with the requirements of Rule 26(a)(2)(B). With that report in hand, and on the basis of the justifiable assumption that the report as submitted may be relied upon as a definitive disclosure of the testimony (including the opinions and bases therefor) of the expert, the opposing party will be in a position . . . to determine whether to arrange for expert testimony from other witnesses . . . .

S.E.C. v. Nacchio, No. 05–cv–00480, 2008 WL 4587240, *2 (D. Colo. Oct. 15, 2008) (internal marks omitted) (quoting *Dixie Steel Erectors, Inv. v. Grove U.S., LLC*, No. CIV-04-390-F, 2005 WL 3558663, *9 (W.D.Ok. Dec. 29, 2005)).

Expert reports must be "detailed" and "complete"; they must "include the substance of

the testimony which an expert is expected to give on direct examination along with the reasons therefor"; opposing counsel should not be "forced to depose an expert in order to avoid ambush at trial" and "sufficiently complete so as to shorten or decrease the need for expert depositions and thus conserve resources"; they "must not be sketchy, vague or preliminary in nature;" and they must include "'how' and 'why' the expert reached a particular result, and not merely the expert's conclusory opinions." *Salgado v. General Motors Corp*., 150 F.3d 735, 742 n. 6 (7th Cir.1998) (internal marks omitted).

"Because the Rule 26(a)(2)(B) disclosures are intended to forecast trial testimony, the *prima facie* showing [of a medical malpractice claim] should be evident through the disclosure of expert reports," *Sharpe*, 230 F.R.D. at 460. Thus, to be complete and detailed, the expert reports must establish the standard of care, whether that standard has been breached, and the causal link (proximate cause) between the claimed negligence and the asserted injuries and damage. *See Fitzgerald*, 679 F.2d at 350 ("Just as negligence or violation of the standard of care must ordinarily rest on expert testimony, so proof of causation–that is that the defendant's negligence was 'more likely' or 'more probably' the cause of the plaintiff's injury–requires expert testimony.").

> "Rule 26 disclosures are often the centerpiece of discovery in litigation that uses expert witnesses. A party that fails to provide these disclosures unfairly inhibits its opponent's ability to properly prepare, unnecessarily prolongs litigation, and undermines the district court's management of the case. For this reason, "[w]e give particularly wide latitude to the district court's discretion to issue sanctions under Rule 37(c)(1)."

Saudi v. Northrop Grumman Corp. 427 F.3d 271, 278-79 (4th Cir. 2005) (internal marks omitted). A failure to provide the proper, full and complete disclosure of an expert's conclusions and opinions warrants automatic exclusion of the expert testimony, unless the failure was

substantially justified or harmless. *Sharpe*, 230 F.R.D. at 458; Rule 37(c)(1), Fed.R.Civ.Pro.

In addition, even if proper disclosure is made, a court may exclude expert opinion testimony that is inadmissible. *Sharpe*, 230 F.R.D. at 460 ("a court may rule on whether an expert's opinion is a type of admissible evidence prior to trial"). An expert's testimony is admissible only if the expert opinion will "help the trier of fact," is "based on sufficient facts or data," is "the product of reliable principles and methods," and "the expert has reliably applied the principles and methods to the facts of the case." F.R.E. 702. Even probative evidence may be excluded if it is outweighed by considerations of, *inter alia*, fairness, confusion, and waste of time. F.R.E. 403.

The Court "must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert*, 509 U.S. at 589. In order to be relevant, the expert testimony in the case must be "sufficiently tied to the facts of the case." *Id*. at 591. "A supremely qualified expert cannot waltz into the courtroom and render opinions unless those opinions are based upon some recognized scientific method and are reliable and relevant under the test set forth by the Supreme Court in *Daubert*." *Clark v. Takata Corp*., 192 F.3d 750, 759 n.5 (7th Cir. 1999).

"[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert." *General Electric v. Joiner*, 522 U.S. 136, 146 (1997). "A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Id*.

An expert must "employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Company, Ltd. v.*

Carmichael, 526 U.S. 137, 152 (1999).

"Since *Daubert* . . . parties relying on expert testimony have had notice of the exacting standards of reliability such evidence must meet." *Weisgram v. Marley Co.*, 528 U.S. 440, 442 (2000).

III. Analysis of Dr. Appelbaum's Written Report and Opinions

Dr. Appelbaum's Report, Exhibit 1, offers a total of five major opinions: three opinions regarding the alleged negligence of Dr. McDaniel, one opinion regarding causation, and one opinion regarding Ms. Grese's sanity at the time she took her life. Sections III. A. - E., *infra*, address each opinion in order.

A. Dr, Appelbaum's Opinion that Dr. McDaniel "Failed to Prescribe Appropriately" Should Be Excluded.

Dr. Applebuam's first major opinion is that: "1) VA staff, including Dr. McDaniel**,** failed to prescribe appropriately for Ms. Grese." Appelbaum 3. That opinion is supported by three supporting opinions, which are addressed *infra.*, Section III.A.2. -A.4., but before turning to those three supporting we opinions, we first address Dr. Appelbaum's over-arching failure to address the appropriate standard of care, i.e., what medication should have been prescribed in order to meet the standard of care applicable to psychiatrists practicing in Virginia in 2010.

1. Standard of Care Not Provided.

Not once throughout Dr. Appelbaum's entire report does he suggest, much less establish, **what** medication should have been prescribed. *See* Appelbaum 3-4. Thus, he fails to establish the applicable standard of care.

In *Sharpe*, one of plaintiff's experts, Dr. Hoffman, submitted an expert report which set forth a chronology.

> . . . This chronology is brief and not very detailed. It generally sets forth a date, Mr. Sharpe's ailment or complaint that occurred on this date, and the corresponding medical treatment. For a number of dates, Dr. Hoffman placed in bold text a notation indicating that treatment was considered but not performed, or that a specific treatment was neither considered nor performed at that time. The inference is that the treatment described in the bolded text should have been performed on Mr. Sharpe.

Sharpe, 230 F.R.D. at 455. This Court found that Dr. Hoffman's report failed to make the necessary *prima facie* showing of the applicable standard of care.

> . . . Perhaps Dr. Hoffman meant that the standard of care to be inferred from his bolded references to the actions not taken by the Veterans Affairs Medical Center staff. If this is the case, it is far too opaque and nonspecific to be of evidentiary value. **The setting forth of the standard of care is a necessary foundation for an opinion that the defendant's agents breached that standard.**

Sharpe, 230 F.3d at 460-61 (emphasis added). *See also Campbell v. United States*, No. 3-10cv363, 2011 WL 588344 at *3 (Feb 8, 2011, E.D.Va.) *aff'd*, 470 Fed.Appx. 153, 156-57 (4th Cir. 2012) (rejecting the notion that the Government could "infer" the standard of care and causation from the expert's report).

Dr. Appelbaum's report does not even reach the level of Dr. Hoffman's failed report. His chronology, Appelbaum 1-3, is similarly "brief and not very detailed." *See Sharpe*, 230 F.3d at 455. He notes that, "Sixty-day prescriptions of quetiapine were filled at VAMC Hampton twice within a 2-day period, on October 19, and 20, 2010." Appelbaum 2-3. Shortly thereafter he opines, "Quetiapine was an inappropriate choice for Ms. Grese's treatment." Appelbaum 3. But no other medications are mentioned, and nowhere in his seven page report is there any bolded text, or regular text, from which it possibly could even be inferred which medications should have been prescribed in order to meet the applicable standard of care. Dr. Appelbaum's statement on the applicable standard of care is not opaque. It does not exist.

Plaintiff's interrogatory answers illustrate the importance of complete expert reports. Following Dr. Appelbaum's report (served on July 31, 2010), Defendant demanded an answer to an outstanding set of interrogatories (served on June 21, 2012). Plaintiff's answers (served August 20, 2010) provided no direct response to Defendant's interrogatory which asked, in part, "What does Plaintiff contend should have been done by [the allegedly negligent provider] in order comply with the relevant standard of care[?]" Plaintiff, at best, merely referred to their previously served expert reports. *See* Plaintiff's Answers to Defendant's Second Set of Interrogatories (August 20, 2010), Exhibit 2. Answering interrogatory questions about expert testimony by referring to a hollow expert report required a deposition of the expert since, in this case, neither the answers nor the report set forth the allegedly applicable standard of care. But the answers and report were so "sketchy and vague" that they prevented the defendant from adequately "preparing for a deposition of" the expert. *See Sharpe*, 230 F.R.D. at 458.

2. Dr. Appelbaum's Supporting Opinions are Incomplete, Irrelevant, Unreliable and Inadmissible.

Dr. Appelbaum offers three supporting opinions in support of his argument that Dr. McDaniel failed to prescribe appropriately for Ms. Grese. *See* Appelbaum 3-4. Those opinions, however, do not provide substantive rationale and lack sufficient reliability. Moreover, Dr. Appelbaum completely fails to link the weak rationale he offers with "that degree of skill and diligence practiced by a reasonably prudent practitioner in the field of [psychiatry] in this Commonwealth." *See* Code of Virginia, 1950, § 8.01-581.20.

First, Dr. Appelbaum argues that, "Of all the available antipsychotic medications, it is the only one that is reported to have abuse potential and, as a result, is sought by persons with a proclivity for substance abuse." Appelbaum 3. In support, he cites to four letters to the editor,

one factually unsupported statement, and one conclusory opinon.

The first letter to the editor, written by Emil R. Pinta, M.D., Columbus, Ohio, and Robert E. Taylor, M.D. Cambridge, Ohio, was published is the American Journal of Psychiatry, 164:1: (January 2007) 174-75. The very first sentence reads: "Quetiapine is not a controlled substance and is not considered addictive." *Id.* at 174.[3] The authors then report that they "have treated a number of inmates who have engaged in drug-seeking and sometimes illegal behavior to obtain" quetiapine. *Id*. They admit that among the reasons for the behavior that they noted, among prisoners, might be because "commonly abused drugs are less readily available" and because "quetiapine treats anxiety and sleeplessness associated with substance use withdrawal – with prisoners having high rates for these disorders." *Id*. They explain:

> . . . However, an internet search yielded a number of self reports by individuals who believe they have become addicted to this agent. There is a popular rap song in which "seroquel" is included in a long list of addictive substances. In street jargon, quetiapine is known as "queli" and "Susie-Q."

Id. This explanation rebuts itself.

The second letter to the editor, written by Joseph M. Pierre, M.D. and three other physicians, all from Los Angeles, California, was published in the American Journal of Psychiatry, 161:9 (September 2004) 1718. It opens, "We would like to report on the widespread 'abuse' of quetiapine among inmates in the Los Angeles County Jail – 'the largest mental health institution in the world.'" *Id*. at 1718. The authors admit that, "the prevalence of this behavior beyond this narrow forensic population is unknown." The authors note that this use by inmates

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[3] Drugs and other substances that have "a potential for abuse" are generally controlled substances. *See* 21 U.S.C. § 811(a). Quetiapine is not a controlled substance. *See* http://www.deadiversion.usdoj.gov/21cfr/21usc/index.html.

"suggests that quetiapine is indeed associated with a better subjective response then its conventional antipsychotic counterparts." *Id*.

The third letter to the editor, written by Brian M. Waters, M.D., and Kaustubh G. Joshi, M.D., both of San Antonio, Texas, was published in the American Journal of Psychiatry, 164:1 (January 2007) 173-174. They report that they "have noted recent reports of quetiapine diversion and misuse among inmates in correctional settings." *Id*. at 173. "The high prevalence of substance use disorders in corrections and the secondary gain of serving out 'easy time' with pharmacological assistance contribute to an underground economy of diverted psychoactive medications." *Id*. "Anecodal reports from colleagues– as well as online testimonials–support the existence of quetiapine diversion and misuse in noncorrectional settings as well." Their only citation in support of that statement is to The Vaults of Erowid, http://erowid.org/ (accessed April 2006). The Executive Director of Erowid is "Fire" Erowid who, along with her partner "Earth," co-founded Erowid.org in 1995. *See* http://www.erowid.org/culture/characters/erowid_fire/ (accessed September 2012). A casual review of the site shows that many, perhaps the substantial majority, of the individual posters are polysubstance abusers reflecting upon their personal experiences with a wide variety of legal and illegal substances, including other antipsychotic medications.

The fourth letter to the editor, written by David Murphy, M.D., Kimberly Bailey, R.N., Michael Stone [professional status not stated], and William C. Wirshing, M.D., all of Culver City, California, was published in the American Journal of Psychiatry, 165:7 (July 2008) 918. Their article lists three references, including two of the letters to the editor described above (from Pierre and Pinta). Murphy, *et al.*, describe an encounter with a single patient who

requested that his quetiapine prescription be refilled. The patient reported that he had been diagnosed with schizophrenia and that "the local police were disturbing his sleep by 'electronically monitoring' his testicles." *Id.* The patient "admitted to both the excessive use and sale ($3.00 per 100mg tablet) of quetiapine." *Id.* The authors speculated that "[i]f the current misuse of the compound continues or expands then ultimately quetiapine could be declared a controlled substance, which would be unfortunate." *Id.*

From these four letters to the editor that Dr. Appelbaum concludes, "to a reasonable medical certainty," Appelbaum 3, that quetiapine "is the only [antipsychotic medication] that is reported to have abuse potential and, as a result, is sought by persons with a proclivity for substance abuse." *Id.*

An expert's report must be "based on sufficient facts or data" and be "the product of reliable principles and methods." F.R.E. 702. Hearsay reports from Earth and Fire, anonymous sources on the internet, prisoners and one schizophrenic cannot reasonably be the basis for a medical finding, to reasonable degree of medical certainty, that quetiapine is abused outside of the prison setting. Whether an opinion has been subjected to "peer review and publication," and whether the theory "enjoys general acceptance within a relevant scientific community" are relevant factors which the trial judge may consider in performing the gatekeeper function. *Kumho Tire Co., Ltd.*, 526 U.S. at 149-50 (internal marks omitted). Dr. Appelbaum's report does not show that these letters were peer reviewed, nor that they enjoy general acceptance within the psychiatric community.

> . . . A fundamental principle of evidence-based medicine . . . is that the strength of medical evidence supporting a theory or strategy is hierarchal. When ordered from strongest to weakest, systemic review of randomized trials (meta-analysis) is at the top, followed by single randomized trials, systemic review of observational

> studies, single observational studies, physiological studies, and unsystematic clinical observations. . . .

John B. Wong, *et al.*, Reference Guide on Medical Testimony, in REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 687, 723-24 (Fed. Judicial Ctr. 3d ed. 2011), available at http://www.fjc.gov/public/pdf.nsf/lookup/SciMan3D01.pdf/$file/SciMan3D01.pdf. These four letters are merely unsystematic clinical observations. Reliance solely on these four letters to editor to establish the standard of care applicable to psychiatrists in Virginia in 2010 demonstrates a failure to exercise "the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *See Kumbo Tire Co., Ltd.*, 526 U.S. at 152.

Dr. Appelbaum offers no evidence that quetiapine has the potential for abuse by women who are not incarcerated, nor that reasonably prudent psychiatrists practicing in Virginia in 2010 ***knew*** that quetiapine had such a potential for abuse that it should not be prescribed. In fact, while Dr. Appelbaum does not provide a full listing of the other instances in 2010 when non-VA psychiatrists prescribed quetiapine to the decedent, his own report shows, "On May 12, 2010, Ms. Grese was discharged from Virginia Beach Psychiatric Center, having been restarted on quetiapine at a total daily dose of 250mg." Appelbaum 2.

Since Dr. Appelbaum does not show that reasonably prudent psychiatrists practicing in Virginia in 2010 ***knew*** that quetiapine had such a potential for abuse that it should not be prescribed, his opinion should be excluded because it is irrelevant (F.R.E. 401), confuses the issue (F.R.E. 402), not helpful to the trier of fact (F.R.E. 701(a)), not based on sufficient facts or data (F.R.E. 701(b)), not the product of reliable principles and methods (F.R.E. 701(c)), and because he has not reliably applied those principles and methods to the facts of this case. F.R.E. 702(d).

Following his citations to the letters to the editors, Dr. Appelbaum then adds that, "Given her extensive history of substance abuse, as well as reports of her drug-seeking behavior in relation to quetiapine, it should never have been prescribed for as it was likely that it would reinforce her drug-abusing behavior." Appelbaum 4. However, no where in his report does Dr. Appelbaum establish that there were "reports of her drug-seeking behavior *in relation to quetiapine*." *See* Appelbaum 1-3 (emphasis added). At best, he says that she was diagnosed with "polysubstance abuse," Appelbaum 1, and was "unable to control her abuse of prescription medications." Appelbaum 2. While defendant admits that the medical record in this case shows that the decedent engaged in "drug-seeking" behavior, quetiapine is just one of the many drugs, legal and illegal, that she used. If Dr. Appelbaum believes that she engaged in drug-seeking behavior *in relation to quetiapine* – an allegation that we deny – then in order to provide "a complete report" he had an obligation to point out where in the records he found a factual basis for that opinion. The expert must submit "a detailed and complete written report, stating the testimony the witness is expected to present during direct examination, together with the reasons therefore." *Sharpe,* 230 F.R.D. at 458 (internal marks omitted).

Moreover, no where in his report are there any bases or reasons for his opinion that quetiapine "likely . . . would reinforce her drug-abusing behavior." This is a purely conclusory opinion which must be excluded. *See Salgado*, 150 F.3d 735, 741 n. 6 (7th Cir.1998) (an expert report must include 'how' and 'why' the expert reached a particular result, and not merely the expert's conclusory opinion) (internal citations omitted).

Second, Dr. Appelbaum argues that, "Quetiapine is a particularly problematic medication for suicidal patients, which is an additional reason why it should not have been prescribed for

Ms. Grese, or at the very least should have been stopped when it was clear that she was engaging in life-threatening suicidal behavior with quetiapine." Appelbaum 4. In support, he cites to one published article and makes one conclusory opinion. The essence of this argument is that quetiapine is more lethal than other antipsychotic medications.

The article, written by Michael A. Ciranni, M.D., Ph.D.; Thomas E. Kearney, Pharm.D.; and Kent R. Olson, M.D., was published in the Journal of Clinical Psychiatry 70:1 (January 2009) 122-29. The article opens:

> Pharmacologic treatment of schizophrenia in the United States is largely dominated by the use of "atypical," or second generation, anti-sychotics (SGAs), which now comprise 90% of the market's share for antipsychotic drugs in the United States. The increased use of SGAs over "typical," or first-generation, antipsychotics (FGAs), has been driven mainly by initial reports of the superior efficacy of SGAs, as well as their seemingly more benign side effect profile. . . .

Id. at 122. (Quetiapine is second-generation antipsychotic drug. *Id*. at 123, Table 1.)

Based upon this article, Dr. Appelbaum argues, "The largest review to date of the toxicity of the antipsychotic medications showed that quetiapine was the most commonly used antipsychotic medication in overdoses reported in the California Poison Control System." Appelbaum 4. Dr. Appelbaum also argues, "Quetiapine has the highest rate of respiratory depression in overdose, and all 3 deaths in this series of almost 2000 cases were associated with ingestions of quetiapine." A superficial review of the article suggests that is true. *Id*. at 127, Table 4 (listing 3 deaths related to the use of quetiapine). A closer review shows that there were only 2 deaths ***caused*** by the use of quetiapine.

> . . . The three deaths reported all involved SGA ingestions, specifically quetiapine. **One of the three deaths on autopsy appeared to be the result of an intracranial hemorrhage, not drug overdose** (although no serum levels were obtained.) The 2 other patients died of pulmonary complications secondary to aspiration pneumonia.

Id. at 125 (emphasis added).

Ciranni, *et al.*, list six second-generation antipsychotic medications: aripiprazole, clozapine, olanzapine, quetiapine, risperidone and ziprasidone.

> **While 2 of the 3 deaths observed in our sample were attributed to quetiapine**, deaths from overdose of risperidone, olanzapine, and clozapine have all been reported, as well as a pediatric case involving ziprasidone. . . .

Id. at 127 (emphasis added). The authors conclude:

> In conclusion, our review of 1975 cases of acute SGA or FGA toxic ingestion revealed that the odds of a major adverse outcome or death were significantly higher with SGAs than with FGAs, suggesting that the SGAs are not safer in acute overdose. The odds of respiratory depression, coma, and hypotension were higher with the SGAs, whereas the odds of dystonia and rigidity were higher with the FGAs. Adverse reactions produced by SGAs, such as CNS depression, may seem more mundane than the dystonia or ligidity that FGAs can produce. However, respiratory depression and coma can be life threatening, and the drugs that cause them should be prescribed with caution.

Id. at 128-29.

The article itself expressly shows why the reported incidence of lethality is skewed against quetiapine. "In this study, the 2 most commonly occurring SGAs, quetiapine and olanzapine, made up over 80% of the SGA sample." *Id*. at 126. In fact, quetiapine made up 59.89% of the SGA sample. *See Id.* at 127, Table 4. Neither the article, nor Dr. Appelbaum, explains the statistical significance of 2 events occurring in 60%, and zero events occurring in 40%, of a population of 1,568 cases. The authors of the article show that, prior to its publication in 2009, it was believed that SGAs (such as quetiapine) were believed to be safer than FGAs. *Id*. at 122 and 128. Based upon their study, they merely suggest "caution." *Id*. at 128-29. Their suggestion for "caution" applied to all second generations antipsychotics, and they did not single out quetiapine for particular caution. *Id*.

Even if there is a suggestion of an extremely weak association between quetiapine and lethality, there is no showing of causation. Neither Ciranni, *et al.*, nor Dr. Appelbaum, make any attempt to bridge from association to causation. *See* David H. Kaye and David A. Freedman, Reference Guide on Statistics, in REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 211, 217-28 ("Observational studies can establish that one factor is associated with another, but work is needed to bridge the gap between association and causation."); *General Electric*, 522 U.S. at 146 ("A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.")

The relevant issue is whether reasonably prudent psychiatrists practicing in Virginia in 2010 ***knew*** that quetiapine was a particularly problematic medication to the extent that it should not be prescribed, not whether one observational study can be found which raises an issue. Dr. Appelbaum's report fails to establish that this single article changed the practice of psychiatrists in Virginia in 2010. Accordingly, his opinion should be excluded because it is irrelevant (F.R.E. 401), confuses the issue (F.R.E. 402), not helpful to the trier of fact (F.R.E. 701(a)), not based on sufficient facts or data (F.R.E. 701(b)), not the product of reliable principles and methods (F.R.E. 701(c)), and because he has not reliably applied those principles and methods to the facts of this case. Rule 702(d).

Third, Dr. Appelbaum argues that, "When a patient engages in a serious suicide attempt by a particular means, every effort should be made to restrict their access to that means." Appelbaum 4. In support of his opinion, as authority he cites only to "a note written the summer before she died indicating that restricting access to the means of suicide was an element of her management plan, and substituting another medication that was likely to be equally or more

effective." *Id*. In his Summary of Psychiatric History, Dr. Appelbaum explains that:

> . . . On July 30, 2010, a suicide assessment report was entered into Ms. Grese's record; it noted her repeated suicide attempts with quetiapine and among the approaches that it called for was to "to limit the means" available to her. However, no effort was made to alter her medication treatment. A "Suicide Review Mental Health Clinical Warning" note on August 1, 2010 recorded a (somewhat inaccurate) warning that she had twice overdosed in March on large amounts of quetiapine.

Appelbaum 2. Both notes were written by social workers, not psychiatrists. Progress Notes, _00690-93, Exhibit 3. Nothing in either note, nor the medical record as whole, show that these two social workers were empowered to establish "her management plan." Social workers are not authorized to prescribe medications, nor may a social worker "in any way infring[e] upon the practice of medicine." Code of Virginia, 1950, § 54.1-3702 ("This chapter shall not be construed as permitting the administration or prescribing of drugs or in any way infringing upon the practice of medicine as defined in Chapter 29 of this title.")

A social worker cannot establish the standard of care for a psychiatrist in Virginia. *See* Code of Virginia, 1950, § 8.01-581.20 (witness must "demonstrate[] expert knowledge of the standards of the defendant's specialty" and "had active clinical practice in either the defendant's specialty or a related field of medicine"). To the extent that these social worker notes can be considered a direction to Dr. McDaniel, or any physician, as to how to practice medicine, the authors lacked the knowledge and the authority to do so. Dr. Appelbaum's reliance upon their notes to support his opinion that Dr. McDaniel had an obligation to follow their direction "restricting access to the means of suicide" is medically, and legally, unsupportable.

Dr. Appelbaum concludes with a remark suggesting that there was "another medication that was likely to be equally or more effective." He does not state ***which*** "medication that was

likely to be equally or more effective." Nor does he show his basis or reasons for opining that there is, in fact, another "medication that was likely to be equally or more effective." Thus, Dr. Appelbaum's conclusory opinion is inadmissible. *See Salgado*, 150 F.3d at 741 n.6.

In summary, Dr. Appelbaum's first opinion – "1) VA staff, including Dr. McDaniel, failed to prescribe appropriately for Ms. Grese" – should be excluded because it is incomplete. It does not state the standard of care and does not fully state his bases and reasons for his opinion. Moreover, his opinion, as tendered in his written disclosure report, will not help the trier of fact, is not based on sufficient facts or data, it is not relevant and it is not reliable.

B. Dr. Appelbaum's Opinion that Dr. McDaniel Failed to "Appropriately Assess and Treat" Should be Excluded.

Dr. Appelbaum's second major opinion is so brief that it can easily be quoted in full:

> 2)VA staff, specifically Dr. McDaniel, failed to appropriately assess and treat Ms. Grese's chronic suicidality. The medical record clearly documents that this was a patient who was subject to ongoing bouts of hopelessness that were exacerbated by significant psychotic symptoms, including auditory command hallucinations to kill herself. The recurrence of suicidality was predictable and called for continuous preventive measures. However, at the time of her discharge from the domiciliary program, the only apparent follow up was weekly group therapy for substance abuse and intermittent visits for renewal of her prescriptions. There does not appear to have been a plan in place for treatment of her multiple other psychiatric disorders or her recurrent suicidality.

Appelbaum 4-5. Dr. Appelbaum fails to state **what** "assessment" was and **what** prescription for "treatment" was required by a reasonably prudent psychiatrist in Virginia in 2010.

Perhaps Dr. Appelbaum wants the Court to infer that Ms. Grese should have been assessed as chronically suicidal. That is not enough. "The setting forth of the standard of care is a necessary foundation for an opinion that the defendant's agents breached the standard of care." *Sharpe*, 230 F.R.D. 461. *See also Campbell*, 2011 WL 588344 at *3 (a "complete statement" of

an expert's opinions is not provided when the report "omits the standard of care").

Dr. Appelbaum offers no "basis or reasons" for his suggestion that Dr. McDaniel failed to assess Ms. Grese's risk of suicide and generally ignores the medical record. In his Summary of Psychiatric History, Appelbaum 1-3, the only direct references to Dr. McDaniel is as follows:

> . . . The pharmacist, Mr. Mui, denies having had contact with Ms. Grese's psychiatrist, Dr. McDaniel, before dispensing the medication;[4] however, Dr. McDaniel maintains he contacted the pharmacist and that the prescription was dispensed at his urging because the patient told him that she was planning to leave town immediately. . . .

Appelbaum 3. Dr. Appelbaum makes no reference to Dr. McDaniel's medication management, observations, assessment and diagnosis made on October 19, 2010. *See* Progress Notes, _00502-05, Exhibit 5. Dr. Appelbaum then continues:

> . . . Ms. Grese was discharged from the domiciliary program on October 20, 2010.[5] At the time, she was judged to be at low risk for suicide. . . .

Appelbaum 4. Dr. Appelbaum omits the fact that neither the decision to discharge Ms. Grese from the domiciliary program, nor the assessment of a "low risk of suicide," was made by Dr. McDaniel, but instead was made by a licensed master social worker who was the Drug Abuse Program Coordinator, and endorsed by a licensed clinical social worker who was the Assistant Chief of the Domiciliary. *See* Progress Notes, _00496-97, Exhibit 7. Dr. Appelbaum makes no mention of Ms. Grese's "above average" progress while a participant in the HVAMC Drug

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[4] In fact, Mr. Mui testified that he did not have a specific memory about this case. Depo. 10:6 - 10:16; 30:24 - 31:18, Exhibit 4 . While Mr. Mui testified that he never contacted Dr. McDaniel, he did not deny the possibility that Dr. McDaniel contacted him. Depo. 16:16 - 16:17; 19:16 - 19:18; 31:12 - 31:18.

[5] In fact, Ms. Grese was discharged on October 22, 2010. Progress Note, _00487-91, at 491, Exhibit 6.

Abuse Program from August 4, through October 22, 2010. *Compare* Appelbaum 1-3 *with* Progress Notes, _00487-91, at 489 Exhibit 6. Dr. Appelbaum makes no mention of the outside, non-VA psychiatrist who independently evaluated Ms. Grese on October 8, 2010. *See* Dr. Harvey L. Nissman's report to the Department of Veterans Affairs, _CF_20067-75, Exhibit 8.[6]

Dr. Appelbaum concludes that "There does not appear to have been a plan in place for treatment of her multiple other psychiatric disorders or her recurrent suicidality." As already noted, he omits any discussion of the substantial residential treatment that Ms. Grese received from August 4 to October 22, 2010. Moreover, he omits any reference to Ms. Grese's unwillingness to participate in the VA's Suicide Risk Management Group. Progress Notes, _00686, Exhibit 9. He omits any reference to Ms. Grese's statement that she "did not want to do the continuation of care 'I am burned out' but was willing to do after care." Progress Notes, _00507-08 at _00508, Exhibit 10.

In a similar case, Dr. Appelbaum presented a similar report:

> . . . Dr. Applebaum [sic] presents Dr. Richards as a highly incompetent psychiatrist, unfamiliar with the basic medical definition of depression or its common symptoms and indifferent to the information he did gather. However, Dr. Applebaum's failure to discuss *in any way* the contents of the 11–page letter and the suicide note suggests a lack of familiarity with the basic facts of the case. *See Shaw by Strain v. Strackhouse*, 920 F.2d 1135, 1142 (3d Cir.1990) (stating that expert opinion in the circumstance of that case should have been based on facts in the record). This apparent ignorance of Doby's writings, which represented crucial

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[6] With regard to Dr. Appelbaum's third supporting opinion, discussed *infra*. Section III, C., Dr. Appelbaum states, "The progress note by Johnny McCall dated October 18, 2010 indicates that the request originated with Ms. Grese, who 'Requests larger Rx so she won'g [sic] be at risk of running oot [sic] of meds as often. . . ." In fact, Ms. Grese's request that she receive a larger quantity of medications so she won't be at risk of running out of medications as often is recorded in Dr. McDaniel's Progress Note, not Mr. McCall's Progress Note. *Compare* McDaniel's October 19, 2010 Progress Note, _00502-05 at _00504, Exhibit 5 *with* McCall's October 18, 2010 Progress Notes, _00505-06, Exhibit 11.

> evidence of her mental state, undermines Dr. Applebaum's conclusions regarding Dr. Richards' actions.

Doby v. DeCrescenzo, 171 F.3d 858, 876 (3rd Cir. 1999) (emphasis in original). *See also Nacchio*, 2008 WL 4587240 at *2 ("An expert is expected to 'work diligently to amass the factual data necessary for his expert analysis' and . . . having done that, will prepare and submit a timely and comprehensive report.")

In summary, Dr. Appelbaum's second opinion – "2) VA staff, specifically Dr. McDaniel, failed to appropriately assess and treat Ms. Grese's chronic suicidality" – should be excluded because it is incomplete. It does not state the applicable standard of care and does not state his bases and reasons. Moreover, his opinion will not help the court as it is not based on sufficient facts or data, is incredibly unreliable, and irrelevant.

C. Dr. Appelbaum's Opinion that Dr. McDaniel "Negligently Prescribed and Dispensed" Should be Excluded.

Dr. Appelbaum's third major opinion, in part, is: "3) VA staff, including Dr. McDaniel, negligently prescribed and dispensed Ms. Grese's quetiapine prescription twice within three days." Appelbaum 5.

Dr. Appelbaum fails to establish **what** amount of quetiapine a reasonably prudent psychiatrists practicing in Virginia in 2010 would have prescribed and permitted to be dispensed. Because he fails to state the applicable standard of care, his opinion should be excluded.

As best as we can deduce, the essence of Dr. Appelbaum's opinion, as to a standard of care, is that a patient should not be permitted to "stockpile a large amount of quetiapine." Appelbaum 5. But without a definition of what "a large amount" is, there is no standard.

Quetiapine comes in 25mg, 50mg, 100mg, 200mg ,300mg, and 400mg tablets.

AsrtraZeneca, Seroquel (quetiapine fumarate) Tablets Highlights of Prescribing Information (revised 12/2011) (unnumbered first page), Exhibit 12. Depending on the indication, recommended doses are 150mg - 800mg daily. *Id*. The standard of care is not limited by the manufacturer's recommended dosage, since the test for malpractice is "that degree of skill and diligence practiced by a reasonably prudent" psychiatrist. Code of Virginia, 1950, § 8.01-580.20.

Dr. Appelbaum accurately reports that Dr. McDaniel prescribed 300mg of quetiapine per day, with a 60 day supply, and then permitted an early re-fill. 300 mg times 60 equals 18 grams; 300mg time 120 equals 36 grams. Appelbaum 5.[9] But in January 2010, a non-VA psychiatrist, Dr. Schreiber prescribed 600 mg per day. Exhibit 13. 600mg times 60 also equals 36 grams. At the time of her death, on about November 11, 2010, Ms. Grese had left over from her January prescription 139.5 tablets of quetiapine, at 100mg each, or 13.95 grams. Exhibit 14. Does 13.95, 18 or 36 grams constitute a "stockpile?" Since Dr. Appelbaum fails to state what amount equals a "stockpile," he fails to state the standard of care and fails to submit an opinion that is complete enough to set forth a *prima facie* case. *See Sharpe*, 230 F.R.D. at 460 ("Because the Rule 26(a)(2)(B) disclosures are intended to forecast trial testimony, the *prima facie* showing [of a medical malpractice claim] should be evident through the disclosure of expert reports.")

As part of his basis and reason for his opinion, Dr. Appelbaum explains:

> In his deposition . . . Dr. McDaniel . . . indicates that his reason [for permitting the early refill] was based on her claim that she intended to leave the area immediately after discharge, before the medications could have arrived by mail. Additionally, she wanted to avoid the bother of refilling her prescription in another city. . . . [H]e could have

[9] Dr. Appelbaum's inaccuracies concerning the prescription refill have already been pointed out, *supra*., at notes 5 and 7.

> encouraged her to remain in town until the medications arrived by mail, or simply to have refilled her current prescriptions when it expired, even if she were out of town. . . .

Appelbaum 5. Dr. Appelbaum omits Dr. McDaniel's rationale for permitting the refill to be dispensed early:

> Based on my concern that every time she had taken an overdose, every time she had attempted suicide, every time she had become psychotic she had first stopped taking the medication, and then after becoming very ill and suffering horribly, then attempted suicide by taking an overdose of the very medication that had been helping her until she stopped it.

McDaniel Depostion 45:9 - 45:16, Exhibit 15. And:

> . . . [M]y biggest concern was not to limit her access to Seroquel, but to make sure that she had it because, by what she told me, every single time she got in trouble and tried to kill herself she had stopped taking the medications . . . . She told me that on two occasions that took place when she was traveling, and she had made suicide attempts or gestures, that she had . . . run out of medication. . . . So my greater concern was not to limit her access to the medication, but to ensure her access to the medications. . . .

McDaneil Depostion 19:12 - 20:20, Exhibit 15.[7]

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[7] Similarly, Dr. Appelbaum omitted Dr. McDaniel's explanation of why he did not prescribe another medication:

> . . . Seroquel had, by her testimony and the best evidence we had, still been the only medication that appeared to have any effect on stopping her mood swings and her psychosis and her depression and her suicidal ideation.

McDaniel Deposition 24:8 - 24:12. Exhibit 15. And:

> . . . All of them got the same story, that quetiapine was the agent that seemed to help, and had so far been the only one that did. And she had had adequate trials of a number of other medications, and the remainder she was not willing to try. She had become ill when she took Valproic Acid, which is the most frequently effective stopper of mood swings. She had become agitated when she took Aripiprazole or Abilify, which frequently works. She became sleepy all of the time when trying to use Ziprasidone. And the alternatives, like Olanzapine, Risperidone, she refused to try. And Carbamazepine we were beginning a trial of, but so far I think – I thought she was spotting in taking it, and she had never gone

Why Ms. Grese claimed that she wanted her medication to be for more than 30 days, or to be refilled early, is not the issue. The issue is whether Dr. McDaniel's clinical judgment that his "greatest concern was not to limit her access to the medication, but to ensure her access to the medication[]," *Id*., was a judgment that would not be made by a reasonably prudent psychiatrist practicing in Virginia in 2010. Dr. Appelbaum's failure to address that issue makes his opinion irrelevant.

In summary, Dr. Appelbaum's third opinion – "3) VA staff, including Dr. McDaniel, negligently prescribed and dispensed Ms. Grese's quetiapine prescription twice within three days" – should be excluded because it is incomplete. It does not state the applicable standard of care. His opinion will not help the court as it is not based on sufficient facts or data, is incredibly unreliable, and irrelevant.

D. Dr. Appelbaum's Opinion on Causation Should be Excluded.

Dr. Appelbaum's fourth major opinion, in total, reads:

> These failures to conform to the standard of care, in my opinion, were directly causative of Ms. Grese's death by quetiapine overdose.

Appelbaum 5.

In *Campbell*, the district court found plaintiff's "expert report deficient, as Dr. Moffatt failed to delineate the applicable standard of care, discuss the issue of causation, explain the factual basis for his conclusions, or reveal the records that he reviewed, as required by Rule

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> to the lab that I had requested to get a level done. So at that point, after trying several medications and not being willing to try the others, she was sort of painted into a corner with Seroquel.

McDaniel Deposition 25:10 - 26:6, Exhibit 15.

26(a)." *Campbell*, 470 Fed. Appx. at 156. The Fourth Circuit upheld the exclusion of the witness. "Absent the rare case in which the alleged negligent act or omission is clearly within the common knowledge of laymen, expert testimony is ordinarily necessary to establish these elements." *Id*. at 158 (internal marks omitted).

Similarly, in *Sharpe*, this Court held:

> [N]either Dr. Hoffman or Dr. Kiev specify what possibly more successful treatment opportunities were foregone by a late diagnosis. This goes directly to causation. The speculative and non-specific reports of Drs. Hoffman and Kiev do not permit any evidentiary inference that the late diagnosis was the cause of the plaintiff's injuries to a reasonable degree of medical certainty. The vague references to "more definite treatment," "increased survival" and "greater . . . potential for intervening" are far too speculative to allow such opinions to go to a jury on the issue of causation." *See Fitzgerald*, 679 F.2d at 350.

Sharpe, 230 F.R.D. at 461.

Dr. Appelbaum fails to explain **how** a different prescription would have saved her life.

Dr. Appelbaum fails to explain **how** a different diagnosis would have saved her life.

Dr. Appelbaum fails to explain **how** a different follow-up plan would have saved her life.

Dr. Appelbaum fails to explain **how** Dr. McDaniel's refusal to authorize an early refill of her prescription would have saved her life.

Without a "complete statement" on his opinion on causation, i.e., on "how" the alleged negligence caused the death of the decedent, and without the "basis and reasons" for that opinion, Dr. Appelbaum's report fails the test of Rule 26(a)(2)(B), Fed.R.Civ.Pro. Without a showing that Dr. Appelbaum's opinion is based on "sufficient facts or data" and is the "product of reliable principles and methods" which have been "reliably applied," Dr. Appelbaum's opinion is inadmissible under F.R.E. 702 and *Daubert*.

E. Dr. Appelbaum's Opinion on Ms. Grese's Mental State Should be Excluded.

Dr. McDaniel's fifth major opinion is also so brief that it can be easily quoted in full:

> . . . Although **no one can know with certainty** what she was thinking at the moment she consumed the fatal overdose of quetiapine, my opinion is that it is more likely than not that Ms. Grese was **not capable of making a rational decision** regarding ending her life. That opinion is based on two bodies of evidence. First, Ms. Grese past suicide events were associated with and driven by psychotic symptoms, including paranoia and command hallucinations ordering her to end her life by quetiapine overdosage. It is more likely than not that the same confluence of symptoms occurred when she took her fatal overdose. Second, based on the email that she sent to her mother on November 8, 2010, Ms. Grese was experiencing paranoid psychotic ideation about the Central Intelligence Agency, which has been a recurring theme when she was psychotic. This provides additional evidence that she had succumbed again to her recurrent psychiatric symptoms shortly before she ended her life.

Appelbaum 5-6 (emphasis added).

While Dr. Appelbaum asserts "to a reasonable medical certainty" that the VA and its employees were negligent, Appelbaum 3, with respect to Ms. Grese's mental state at the time of her death, he advances that "**no one can know with certainty** what she was thinking." Appelbaum 4 (emphasis added). While Dr. Appelbaum then offers "my opinion is that it is more likely than not that Ms. Grese was capable of making a rational decision regarding ending her life," *Id*., that mere opinion stripped of medical certainty is inadmissible. As explained in *Fitzgerald*,

> . . . It would appear, therefore, that the authorities establish, and the plaintiff accepts, the rule that only if the opinion evidence on causation, as offered by the plaintiff, rises to the level of a "reasonable degree of medical certainty" that it was more likely that the defendant's negligence was the cause than any other cause, is there sufficient evidence on causation to permit jury submission on causation.

Fitzgerald, 679 F.2d at 351. "The opinion of a medical expert is evidence." *Id*. at 350 (citations omitted). The opinion of a medical witness, absent a reasonable degree of medical certainty, is just the opinion of a lay witness and thus is inadmissible. *See also Young v. U.S.*, 667 F.Supp.2d

554, 562 (D.Md. 2009) ("Under the applicable federal sufficiency standard, the Court may find adequate evidence to create a triable issue of fact with respect to causation only if expert opinion evidence establishes to a reasonable degree of medical certainty that defendant's negligence was more likely the cause of plaintiff's injuries than any other cause.")

Even if admissible, Dr. Appelbaum's opinion is irrelevant. Under Virginia law, "the term 'insane' refers to one who is, at a given time, an 'idiot, lunatic, *non compos mentis* or deranged.'" *Brown v. Harris*, 240 F.3d 383, 387 (4th Cir. 2001) (internal marks omitted). There is an enormous difference between one who, as Dr. Appelbaum opines Ms. Grese was, "not capable of making a rational decision," and one who is "insane." Being "not capable of making a rational decision" is not a recognized mental disorder. Even if irrationality was a recognized mental disorder, "In most situations, the clinical diagnosis of a DSM-IV mental disorder is not sufficient to establish the existence for legal purposes of 'mental diseas[e]' or 'mental defect." *Clark v. Arizona*, 548 U.S. 735, 775-76 (2006). Virginia follows the *M'Naughten* rule, which requires "a mental disease or defect such that he did not know the nature and quality of the act he was doing, or, if he did know it, he did not know what he was doing was wrong." *White v. Commonwealth*, 636 S.E.2d 353, 356 (Va. 2006). Dr. Appelbaum does not opine that the decedent did not know what she doing, i.e., that her act was not intentional. Nor does Dr. Appelbaum opine that she did not know what she was doing was wrong. While Dr. Appelbaum speculates that her irrationality was the product of paranoia and psychosis, it is only if the psychosis is of such a degree as to meet the legal definition of "insanity" that Dr. Appelbaum's opinion is relevant.

Dr. Appelbaum's opinion is not only uncertain, and thus unreliable, but it addresses the

wrong test, and thus is irrelevant. For both reasons, it is inadmissible.

CONCLUSION

While Dr. Appelbaum is undoubtedly "[a] supremely qualified expert," *see Clark*, 192 F.3d at 759 n.5, he has failed to "work diligently to amass the factual data necessary for his expert report and . . . submit a . . . comprehensive report complying fully with the requirements of Rule 26(a)(2)(B)." *Nacchio*, 2008 WL 4587240, * 2. Thus, pursuant to Fed.R.Civ.P. 37(c)(1), his report must be excluded and he must be prohibited from testifying.

Moreover, Dr. Appelbaum reliance upon letters to the editor and a single observational survey do not satisfy the "same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Company, Ltd.*, 526 U.S. at 152. His opinions are thus unreliable and inadmissible.

With respect to his opinions on negligence, Dr. Appelbaum fails to identify the applicable standards of care for a reasonably prudent psychiatrist practicing in Virginia in 2010. *See* Code of Virginia, 1950, § 8.01-581.20; *Sharpe*, 230 F.R.D. at 460. His opinions are thus irrelevant and inadmissible.

Respectfully submitted,

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Certificate of Service

I hereby certify that on the 20th day of September, 2012, I will electronically file the foregoing with the Clerk of Court using the CM/ECF system, which will then send a notification of such filing (NEF) to the following:

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